Proposed Amendment to the Court's Remedial Order of July 11, 2019
(as modified by the Court's Orders of August 12, 2019 and April 22, 2020)

1. the FDA shall require that, for new tobacco products on the market as of the August 8, 2016 effective date of the Deeming Rule ("New Products"), applications for marketing orders must be filed by September 9, 2020;
2. New Products for which applications have not been filed within this period shall be subject to FDA enforcement actions, in the FDA's discretion;
3. New Products for which applications have been timely filed may remain on the market without being subject to FDA enforcement actions for a period not to exceed one year from the date of application while FDA considers the application;
4. The FDA shall have the ability to exempt New Products from filing requirements for good cause on a case-by-case basis.
5. This order does not restrict the FDA's authority to enforce the premarket review provision against deemed products, or categories of deemed products, before the close of either the 10-month application submission period or the FDA application review period described above.
6. Beginning March 15 or two weeks after the Court rules on Plaintiffs' Rule 60(b)(5) motion (whichever is later), FDA will submit a status report to Plaintiffs and the Court every 90 days.
7. For the purpose of the following paragraph, "Covered Applications" means all applications for New Products for which pending applications for marketing orders were filed by September 9, 2020 that are (a) sold under the brand names JUUL, Vuse, NJOY, Logic, Blu, SMOK, Suorin, or Puff Bar, or (b) reach 2% of total "Retail $ Sales" in Nielsen's "Total E-Cig Market & Players" or "Disposable E-Cig Market & Players" reports before FDA has completed its review of existing Status Report Products.
8. OPTION A: The first status report will provide date ranges when FDA expects to take action (defined as the issuance of a marketing order, refuse-to-accept letter, refuse-to-file

letter, or marketing denial order) on each manufacturer's Covered Applications. Date ranges may be April 2022, May 2022, June 2022, and quarterly thereafter. Subsequent status reports will report any revisions to prior estimates, including an explanation, with specificity, for any revisions that delay or reduce FDA's prior estimates of completion.

9. OPTION B: The first status report will state the percentage of Covered Applications on which FDA expects to have taken action (defined as the issuance of a marketing order, refuse-to-accept letter, refuse-to-file letter, or marketing denial order) by June 2022, and quarterly thereafter. Subsequent status reports will report any revisions to prior estimates.